

REMARKS

Applicants appreciate their attention being called to the lack of clarity in claim 68; this has been resolved by amendment. It was intended that the last phrase of that claim modify the isolated polypeptide claimed not the PHELIX protein having an amino acid sequence of SEQ. ID. No.: 2. Accordingly, claim 68 has been amended to clarify that it is the isolated peptide that is at least 90% identical to the amino acid sequence of SEQ. ID. No.: 2 over its entire length and, in addition, that peptide is characterized by having only conservative substitutions. Applicants have also noticed that claim 60 contained this same ambiguity and this has been addressed by amendment as well. As the amendments are for clarification only and do not change the scope of the subject matter claimed, it is believed no new issues are raised and the claims are in a better position for allowance and appeal. Accordingly, entry of the amendment is respectfully requested.

The Rejections Under 35 U.S.C. § 112, Paragraph 2

This rejection, directed to claims 68-69 has been addressed by amendment. Although this rejection indicates that the Office has interpreted the claim to indicate that it is the PHELIX protein having an amino acid sequence of SEQ. ID. No.: 2 (which characterizes the antigen to the antibody) that has the conservative substitutions, the “new matter” rejection following in the Office action indicates that the Examiner properly understood the claim as intending that it is the isolated peptide with the 90% identical amino acid sequence that is characterized by conservative substitutions. This verifies that no new issues are raised by the amendment.

The Rejections Under 35 U.S.C. § 112, Paragraph 1 (New Matter)

The Office objects that the specification does not disclose a polypeptide that has 90% identity to SEQ. ID. No.: 2 over the entire length of this sequence. However, the application as

filed made such a claim in claim 3. As the Office is aware, the claims constitute part of the specification. Therefore, this limitation was described in the application as originally filed and cannot constitute new matter. In addition, page 14, line 17, specifically discloses this degree of identity. Further, the very next sentence states that these variants which have 90% or more identity contain conservative amino acid substitutions. The paragraph at page 14, beginning at line 26, further describes specifically what these conservative amino acid substitutions are. In view of the support found in the specification, applicants respectfully submit that claims 68 and 69 do not contain new matter. *Just*

It is also respectfully noted that the requirement for at least 90% identity over the entire length in claim 68 was present in that claim prior to the amendment in the previous response.

The Rejection Under 35 U.S.C. § 101 (Utility)

All claims were rejected on this basis assertedly for reasons of record. This basis for rejection is apparently maintained because the Office has refused to consider the declaration of Dr. Challita-Eid since applicants inadvertently failed to include the papers referenced in the declaration along with the previous response. Respectfully, applicants would have appreciated it if the Examiner had telephoned the undersigned representative and requested these exhibits rather than simply refusing to consider the declaration. This is especially the case as the rejection has now been made final. In addition, it is not believed that the lack of inclusion of these published papers is a ground for refusal to consider a declaration. All of these documents are publicly available and had the Office doubted the declarant's characterization of them, they could readily have been obtained by the Office itself.

Nevertheless, accompanying the present response is a complete set of the exhibits attached to Dr. Challita-Eid's declaration. Applicants respectfully request that this declaration

now be considered and that the finality of the rejection be withdrawn. Respectfully, applicants believe that the Office had the responsibility to consider this declaration in view of the foregoing. This declaration has been characterized extensively in applicants' previous response which is incorporated herein by reference and a copy of the relevant portions of which are included as an attachment hereto for the convenience of the Examiner.

To summarize briefly here, the Office assumes that the claimed PHELIX proteins do not have the asserted utility of allowing detection of cancer cells through detection of the production of these proteins because the data in the specification related to the expression of the gene encoding the PHELIX protein in cancer cells are based on the detection of mRNA rather than the protein itself. The Office asserts that there is no correlation between mRNA production and protein production. This assertion has been demonstrated as false both by the previously submitted declaration of Dr. Rene Hubert and by the as yet to be considered declaration of Dr. Challita-Eid.

The Rejection Under 35 U.S.C. § 112, Paragraph 1 (Enablement)

All claims were rejected under this paragraph for the same reasons as those set forth under the rejection based on lack of utility above. Accordingly, the arguments set forth above are equally applicable here.

Request for Withdrawal of Finality

Applicants respectfully request that the finality of the previous rejection be withdrawn. This request is on the basis that it was the obligation of the Office to consider the declaration of Dr. Challita-Eid submitted with the previous response. None of the exhibits which were inadvertently not submitted with the declaration were unavailable to the Office; further, the documents, which were publicly available journal articles, were characterized in the declaration,

made under oath. Applicants believe they are entitled to have this declaration considered before final rejection is made.

CONCLUSION

Claims 60 and 68 have been amended for clarification; the amendment to claim 68 disposes of the rejection under 35 U.S.C. § 112, paragraph 2, for asserted lack of clarity. The Office correctly characterized the intended meaning of claim 68 in the rejection made under 35 U.S.C. § 112, paragraph 1, thus indicating no new issues are raised by this amendment.

Support has been shown for the limitations of claim 68 in the application as originally filed, so the rejection under 35 U.S.C. § 112, paragraph 1, for asserted new matter may be withdrawn.

The rejection under 35 U.S.C. § 101/112 for asserted lack of utility is addressed by the arguments made in the previous response and by the declaration of Dr. Challita-Eid. It is believed that these arguments supported by the testimony of Dr. Challita-Eid are dispositive of this rejection. The rejection is grounded in the notion that there is no correlation between expression of mRNA and production of protein; the testimony of Dr. Challita-Eid demonstrates that this notion is incorrect. Accordingly, this basis for rejection may be withdrawn.

In any event, the finality of the rejection should be withdrawn in view of the failure of the Office properly to consider Dr. Challita-Eid's declaration.

In light of the foregoing, it is believed that claims 54-55, 60-61, 68-69 and 74-77 are in a position for allowance and passage of these claims to issue is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to

charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket No. 511582002700.

Respectfully submitted,

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Attachments: Documents referenced in Challita-Eid's declaration.
Copy of pages 6-10 of Response filed 13 June 2002.

EXHIBIT A. - VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

60. (Twice amended) An isolated polypeptide of at least 15 contiguous amino acids of the sequence shown in SEQ ID NO: 2, which comprises amino acid residues 140-154 of SEQ ID NO: 2 wherein the polypeptide is recognized by an antibody that specifically binds a PHELIX protein having the amino acid sequence of SEQ ID NO: 2[, and which comprises amino acid residues 140-154 of SEQ ID NO: 2].

68. (Twice amended) An isolated polypeptide that is at least 90% identical to the amino acid sequence of SEQ ID NO: 2 over the entire length of SEQ ID NO: 2[, and that is a conservative substitution mutant of a protein having the amino acid sequence of SEQ ID NO: 2 wherein the polypeptide is recognized by an antibody that specifically binds a PHELIX protein having the amino acid sequence of SEQ ID NO: 2 [that is a conservative substitution mutant of a protein having the amino acid sequence of SEQ ID NO: 2].